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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SISSON, BRADLEY L	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,822	REMACLE ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45,48 and 50-88* is/are pending in the application.

4a) Of the above claim(s) *1-44 and 85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,48,50-84 and 86-88* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 December 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 May 2005 has been entered.

Election/Restrictions

2. In the response of 23 September 2003, applicant's representative elected the invention of Group II, with nucleotide sequences as the elected species. Claim 45, as amended, clearly contains new language directed to non-elected species.

3. Applicant is required to cancel the non-elected species from the claim or take other appropriate action.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45, 48, 50-84, and 86-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Attention is directed to the decision in *University of Rochester v. G.D. Searle & Co.* 68 USPQ2D 1424 (Fed. Cir. 2004) at 1428:

> To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. Vas-Cath, 935 F.3d at 1563; see also Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); In re Gosteli, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572.

For convenience, claim 45, the sole independent claim under consideration, is reproduced below.

45. **(Currently amended)** A compact-disc (CD) comprising:

~~registered data, and bound upon its surface,~~ one or more ~~non-cleavable~~ capture molecule(s) bound to a specific surface area of said disc, wherein said capture molecule(s) do(es) not comprise a cleavable spacer, ~~which allow~~ said capture molecule(s) providing a site for specific binding with one or more target molecule(s) to be detected, identified and/or quantified, wherein said capture and target molecules are selected from the group consisting of antibodies, proteins, receptors, ligands of said receptors, nucleic acids useful as diagnostic agents, nucleic acids useful for detecting presence of a pathogenic organism, and nucleic acid probes, wherein said nucleic acid probes are from nucleic acids encoding polypeptides, said polypeptides selected from the group consisting of enzymes, transcription factors, structural proteins, transporters, antibodies, antigens, receptors, markers of toxicity, bacterial markers, viral markers, oncogenes, tumor suppressors, senescence markers, tumor necrosis factors, proteins involved in apoptosis, inflammation, DNA damage and repair, oxidative stress, metabolism, and cell cycle; and

registered data concerning characteristics of the capture molecules or concerning treatment of a signal which results from binding between the target molecule(s) and the capture molecule(s), wherein said registered data is binary data.

5. A review of the instant application finds where a Sequence Listing was filed on 30 August 2004, and that it comprised but four primer sequences. A review of the disclosure fails to find an adequate written description of the genera now set forth in Claim 45. Specifically, claim 45 now recites that the CD comprises "capture and target molecules [that] are selected from the group consisting of antibodies, proteins, receptors, ligands of said receptors, nucleic acids useful as diagnostic agents, nucleic acids useful for detecting presence of a pathogenic organism, and nucleic acid probes, wherein said nucleic acid probes are from nucleic acids encoding polypeptides, said polypeptides selected from the group consisting of enzymes,

transcription factors, structural proteins, transporters, antibodies, antigens, receptors, markers of toxicity, bacterial markers, viral markers, oncogenes, tumor suppressors, senescence markers, tumor necrosis factors, proteins involved in apoptosis, inflammation, DNA damage and repair, oxidative stress, metabolism, and cell cycle."

6. A review of the specification fails to find an adequate written description of the myriad amino acid and nucleotide sequences encompassed by each of the recited genera. While an applicant is not required to provide a detailed description (e.g., sequence) for each embodiment (species) encompassed by the claims, the specification must provide an adequate written description of a sufficient number of species so as to reasonably suggest that applicant had possession of the invention at the time of filing. In support of this position attention is directed to the decision in *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

> It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. In re Soll, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; In re Wahlforss et al., 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.
>
> ***
>
> We are of the opinion that a genus containing such a large number of species cannot properly be identified by the mere recitation or reduction to practice of four or five of them. As was pointed out by the examiner, four species might be held to support a genus, if such genus is disclosed in clear language; but where those species must be relied on not only to illustrate the genus but to define what it is, the situation is otherwise.

Here, the claims fairly encompass billions of species, not just hundreds, as discussed in *Shokal*. The presence of four primers in the Sequence Listing does not constitute an adequate written description of the claimed invention. Therefore, and in the absence of convincing evidence to the contrary, the specification is deemed not to provide an adequate written description of the CD as claimed (claims 45, 48, 50-69). Similarly, the specification does not reasonably suggest that applicant was in possession of the claimed kit (claims 73, 86, and 88) that must comprise said CD.

7. It is noted that claims 70-72 and 87 are drawn to a method of making the disc. As indicated above, the specification does not provide an adequate written description of "capture and target molecules [that] are selected from the group consisting of antibodies, proteins, receptors, ligands of said receptors, nucleic acids useful as diagnostic agents, nucleic acids useful for detecting presence of a pathogenic organism, and nucleic acid probes, wherein said nucleic acid probes are from nucleic acids encoding polypeptides, said polypeptides selected from the group consisting of enzymes, transcription factors, structural proteins, transporters, antibodies, antigens, receptors, markers of toxicity, bacterial markers, viral markers. oncogenes, tumor suppressors, senescence markers, tumor necrosis factors, proteins involved in apoptosis, inflammation, DNA damage and repair, oxidative stress, metabolism, and cell cycle."

8. Argument is provided at page 14 of the response received 25 May 2005 that "as of December 30, 1997 those skilled in the art would appreciate that the application contained sufficient description of how to bind any desired nucleic acid to the surface of the disc."

9. The above argument has been fully considered and has not been found persuasive for in order for the skilled artisan to be able to bind nucleic acids that have the requisite properties, one

must have those specific nucleic acids in their possession. It is not enough that the skilled artisan would be able to understand the general concept of how nucleic acids can be reacted such that they are bound to a support. Rather, the skilled artisan must also have an adequate written description of the nucleic acids that have the requisite properties. As shown above, however, the specification fails to provide an adequate written description of these claimed nucleic acids (essential component of the CD of claim 45). Therefore, and in the absence of convincing evidence to the contrary, the specification is deemed not to provide an adequate written description of the claimed invention.

10. The specification also fails to provide an adequate written description of the detection and/or reading device (claims 74-81) and or the handling device (claims 82-84). Page 66, lines 24-26, teaches that "[t]he reader device is based on a commercially available CD writer (Fig. 12-13)" (emphasis added). Page 8, lines 6-7, states:

> Figures 11 to 14 show various types of Bio-CD reading devices.

A review of the disclosure fails to locate and adequate written description of either the claimed "detection and/or reading device" or of the claimed handling device, including the software that is required for its operation. While the claimed invention may be "based on commercially available CD writer," the specification must provide an adequate written description of the invention in terms of what it is, including all elements of its claimed structure such that the disclosed device will in fact function as intended and claimed. Such detailed description, including that of the interrelatedness of the elements and of the programming even at the level of a general conceptual flow diagram, are not to be found in the original disclosure, nor in the priority document. It appears that applicant is attempting to satisfy the written description

requirement of 35 USC 112, first paragraph, through obviousness. Obviousness, however, cannot be relied upon for satisfaction of the written description requirement. In support of this position, attention is directed to the decision in *University of California v. Eli Lilly and Co.* (Fed. Cir. 1997) 43 USPQ2d at 1405, citing *Lockwood v. American Airlines Inc.* (Fed. Cir. 1997) 41 USPQ2d at 1966:

> Recently, we held that a description which renders obvious a claimed invention is not sufficient to satisfy the written description requirement of that invention.

11. For the above reasons, and in the absence of convincing evidence to the contrary, the specification is not deemed to provide an adequate written description of the claimed inventions and as such does not reasonably suggest that applicant was in possession of the inventions at the time of filing.

12. Claims 45, 48, 50-84, and 86-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute

> even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

13. As set forth above, the specification does not reasonably suggest that applicant was in possession of the invention at the time of filing. It is well settled that one cannot enable an invention that they do not yet possess.

14. As presently worded, the CD of claim 45 is to comprise comprises "capture and target molecules [that] are selected from the group consisting of antibodies, proteins, receptors, ligands of said receptors, nucleic acids useful as diagnostic agents, nucleic acids useful for detecting presence of a pathogenic organism, and nucleic acid probes, wherein said nucleic acid probes are from nucleic acids encoding polypeptides, said polypeptides selected from the group consisting of enzymes, transcription factors, structural proteins, transporters, antibodies, antigens, receptors, markers of toxicity, bacterial markers, viral markers, oncogenes, tumor suppressors, senescence markers, tumor necrosis factors, proteins involved in apoptosis, inflammation, DNA damage and repair, oxidative stress, metabolism, and cell cycle."

15. The specification, as noted above, does not reasonably suggest that applicant was in possession of the tremendous genera encompassed. Further, the specification is silent as to how each of these various compounds are to be used, and information derived from same is to be processed and interpreted. The situation at hand is analogous to that in *Genentech v. Novo Nordisk A/S* 42 USPQ2d 1001. As set forth in the decision of the Court:

> " '[T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.' *In re Wright* 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.*, 927 F. 2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed Cir. 1991); *In re Fisher*, 427 F. 2d 833, 166 USPQ 18, 24 (CCPA 1970) ('[T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.').
>
> *****
>
> "Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (starting, in context of the utility requirement, that 'a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.') Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.
> "It is true . . . that a specification need not disclose what is well known in the art. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. <u>However, when there is no disclosure of any specific starting material or any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art.</u> It is the specification, not the knowledge of one skill in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research. (Emphasis added)

16. Accordingly, and in the absence of convincing evidence to the contrary, claims 45, 48, 50-84, and 86-88 are rejected under 35 U.S.C. 112; first paragraph, as failing to comply with the enablement requirement.

Response to argument

17. The response of 25 May 2005, including the declaration, assert that the invention is adequately described and is fully enabled. This argument has been fully considered and has not been found persuasive for the specification does not teach the starting materials other than in general functional terms. And in any event, the specification does not teach how the results obtained from any CD, assuming *arguendo*, that meaningful results could be obtained, are in fact to be interpreted such that a useful result is obtained. While the specification dos disclose four primers, the CD is to comprise "capture and target molecules [that] are selected from the group consisting of antibodies, proteins, receptors, ligands of said receptors, nucleic acids useful as diagnostic agents, nucleic acids useful for detecting presence of a pathogenic organism, and nucleic acid probes, wherein said nucleic acid probes are from nucleic acids encoding polypeptides, said polypeptides selected from the group consisting of enzymes, transcription factors, structural proteins, transporters, antibodies, antigens, receptors, markers of toxicity, bacterial markers, viral markers, oncogenes, tumor suppressors, senescence markers, tumor necrosis factors, proteins involved in apoptosis, inflammation, DNA damage and repair, oxidative stress, metabolism, and cell cycle." The specification is silent as to what values are to be derived from the CD when used in an assay when the starting material(s) can be from virtually any source (e.g., any plant, any microbe, any virus, any animal, etc.), or how they are to

be interpreted. Similarly, the specification is essentially silent s to how the claimed readers, handling devices, and kits are to be made when the starting materials are not known. The argument of applicant's representative, and the declaration fails to present convincing evidence that the claimed inventions are fully enabled by the disclosure. Therefore, and in the absence of convincing evidence to the contrary, claims 45, 48, 50-84, and 86-88 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson
Primary Examiner
Art Unit 1634

BLS
17 August 2005